PMA Monthly approvals from 3/1/2016 to 3/31/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150028	03/25/2016	PMAO - PMA Origi	CHEATHAM PLATINUM STENT SYSTEM	NUMED, INC.	Approval for the Cheatham Platinum (CP) Stent System, including the CP Stent, Mounted CP Stent, Covered CP Stent, and Covered Mounted CP Stent. The CP Stent and Mounted CP Stent are indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery and balloon angioplasty is contraindicated or predicted to be ineffective. The Covered CP Stent and Covered Mounted CP Stent are indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: Acute or chronic aortic wall injury Nearly atretic descending aorta of 3 mm or less in diameter A non-compliant stenotic aortic segment found on pre-stent balloon dilation A genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810006/S068	03/29/2016	Y - 135 Review Tra	COLLASTA ABSORBABLE COLLAGEN HEMOSTATIC SPONGE, COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORP.	Approval for a change to the collagen processing equipment cleaning protocol.
P840002/S013	03/24/2016	O - Normal 180 Day	TAP SYSTEM 2A	CARDIOCOMMAND, INC.	Approval for a manufacturing site located at Cardiocommand, Inc., in Tampa, Florida, for the manufacture of the Tapsystem Model 2A device.
P840062/S052	03/29/2016	Y - 135 Review Tra	COLLACOTE, COLLATAPE, COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC.	Approval for a change to the collagen processing equipment cleaning protocol.
P850010/S067	03/29/2016	Y - 135 Review Tra	HELISTAT, HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	COLLA-TEC, INC.	Approval for a change to the collagen processing equipment cleaning protocol.
P850035/S042	03/18/2016	S - Special CBE	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Approval for the addition of the following contraindication to the labeling: Any case where SpF Spinal Fusion Stimulators could come into contact with metallic implant components (i.e., those that contain a mixture of Titanium, Cobalt Chrome, and Stainless Steel).
P870076/S018	03/22/2016	O - Normal 180 Day	FALOPE-RING BAND CONTRACEPTIVE TUBAL OCCLUSION SYSTEM	GYRUS ACMI, INC.	Approval for a manufacturing site located at 9600 Louisiana Avenue North, Brooklyn Park, MN 55445 for the production of the Falope Ring Band.
P900033/S051	03/29/2016	Y - 135 Review Tra	INTEGRA ARTIFICIAL SKIN DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Approval for a change to the collagen processing equipment cleaning protocol.
P930039/S123	03/18/2016	N - Normal 180 Day	CAPSUREFIX NOVUS, LEAD AND CAPSUREFIX , NOVUS MRI SURESCAN AND VITATRON CRYSTALLINE LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a design change to the lead helix electrode and a manufacturing site change and the related update to analytical methods and tightened specifications proposed for drug related elements of the medical devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P940016/S020	03/17/2016	Y - 135 Review Tra	H.E.L.P. PLASMAT FUTURA SYSTEM	B. BRAUN AVITUM AG	Approval for a change in manufacturer for your sodium chloride and acetate buffer solution bags.
P960040/S361	03/28/2016	Y - 135 Review Tra	DYNAGEN ICD Models D150, D151, D152, D153; INOGEN ICD Models D140,	BOSTON SCIENTIFIC	Approval for a modification to the charge time ratio limit for the high voltage capacitor.
P960040/S363	03/03/2016	R - Real-Time Proc	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, NG3 EXTENDED LIFE ICD: DYNAGEN, INOGEN, ORIGEN, NG2 5 MINI ICD DYNAGEN, INOGEN,	BOSTON SCIENTIFIC	Approval for updates to the Physicians Technical Manuals for ICDs and CRT-Ds
P970051/S133	03/16/2016	N - Normal 180 Day	NUCLEUS CI532 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new member of the CI500 series implant family in the Nucleus® Cochlear Implant System, the CI532 cochlear implant.
P980016/S565	03/10/2016	R - Real-Time Proc	EVERA MRI; EVERA S DR;EVERA XT DR; EVERA XT VR; MAXIMO II; PROTECTA; PROTECTA XT; SECURA ICDS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of a passivation layer to the XD429 component used in the hybrid charging circuit and the associated manufacturing changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S452	03/01/2016	R - Real-Time Proc	ADVISA DR IPG; ADVISA DR MRI IPG	MEDTRONIC INC.	Approval for a modified shield fastener bracket.
P000008/S034	03/03/2016	O - Normal 180 Day	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Approval of the following changes to the post-approval study for the device: revisions reflecting alignment of protocol terminology with terms used in the electronic data management system and points of clarification based on IRB input.
P000008/S037	03/28/2016	O - Normal 180 Day	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Approval of the post-approval study protocol.
P010012/S406	03/28/2016	Y - 135 Review Tra	DYNAGEN CRT-D Models G150, G151, G154, G156, G158; INOGEN CRT-D	BOSTON SCIENTIFIC CORP.	Approval for a modification to the charge time ratio limit for the high voltage capacitor.
P010012/S409	03/03/2016	R - Real-Time Proc	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR, NG3 CRT-D DYNAGEN CRT-D & X4 CRT-D, INOGEN CRT-D & X4 CRT-D. ORIGEN CRT	BOSTON SCIENTIFIC CORP.	Approval for updates to the Physicians Technical Manuals (PTMs) for ICDs and CRT-Ds
P010023/S013	03/22/2016	Y - 135 Review Tra	SOUNDTECH DIRECT AND MAXUM	OTOTRONIX, LLC	Approval for a test fixture and inspection process change for the Magnet Canister Assembly (MCA).
P010031/S526	03/10/2016	R - Real-Time Proc	BRAVA;BRAVA QUAD; CONCERTO II;CONSULTA;MAXIMO II;PROTECTA;PROTECTA XT;VIVA QUAD S;VIVA QUAD XT;VIVA S;VIVA XT CRT-DS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of a passivation layer to the XD429 MOSFET used in the hybrid charging circuit and changes in the manufacturing process of the XD429

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S108	03/07/2016	R - Real-Time Proc	EXTERNAL PULSE GENERATOR, 16 CHANNEL, EXTERNAL PULSE GENERATOR, 2 PORT HEADER	St. Jude Medical	Approval for changes to the packaging configuration of the External Pulse Generator, 2Port Header (Model3032) used with the External Pulse Generator (Model3599). Specifically, the proposal to remove a component, the magnet, from the EPG header kit (model 3032) to allow for separate distribution. In addition, also requested updates to the EPG Clinicians manual and the MLTC Clinicians manual.
P010032/S110	03/22/2016	R - Real-Time Proc	EXTERNAL PULSE GENERATOR, 2 PORT HEADER, ADHESIVE POUCH, EPG; NON-ADHESIVE POUCH WITH BELT.	St. Jude Medical	Approval for a material change to the approved pouch used with the External Pulse Generator, 16 Channel (Model 3599).
P020045/S074	03/11/2016	R - Real-Time Proc	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval of a new part number and component specifications for an internal USB memory drive to address field reports related to inadequate USB drive performance
P030002/S035	03/24/2016	O - Normal 180 Day	CRYSTALENS AND TRULIGN TORIC INTRAOCULAR LENSES (IOLS)	BAUSCH & LOMB, INC.	Approval for a manufacturing site located at Bausch & Lomb, Incorporated, 21 Park Place Boulevard North, Clearwater, Florida 33759 as an alternate manufacturing facility for the Crystalens and Trulign IOLs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030036/S082	03/03/2016	N - Normal 180 Day	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for shelf life extension.
P030040/S009	03/11/2016	N - Normal 180 Day	ADVIA CENTAUR AHBCM ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur® HBc IgM Assay (ADVIA Centaur® HBc IgM ReadyPack Reagents and ADVIA Centaur® HBc IgM Quality Control Materials) to the ADVIA Centaur® XPT system.
P040012/S056	03/04/2016	O - Normal 180 Day	RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Approval of the following changes to the post-approval study for the device: request to modify the conditions of approval follow-up requirement from 3 to 2 years.
P040040/S026	03/18/2016	O - Normal 180 Day	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORP.	Approval of the following changes to the post-approval study for the device: plan to increase subject enrollment utilizing retrospective data collection.
P040044/S070	03/10/2016	R - Real-Time Proc	MYNX ACE VASCULAR CLOSURE DEVICE (MYNX ACE)	ACCESS CLOSURE, INC.	Approval for an extension of the Mynx Ace Vascular Closure Device shelf life to 18 months.
P060022/S022	03/11/2016	Y - 135 Review Tra	AKREOS INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for the addition of an alternate packaging component supplier for the Akreos Plastic Vial Components.
P070014/S048	03/11/2016	N - Normal 180 Day	LIFESTENT VASCULAR STENT SYSTEMS	BARD PERIPHERAL VASCULAR, INC.	Approval of a 250 mm stent length.
P080009/S012	03/15/2016	R - Real-Time Proc	SEDASYS COMPUTER-ASSISTED PERSONALIZED SEDATION SYSTEM	ETHICON ENDO-SURGERY, INC.	Approval for software changes to address previous software anomalies (modifications to the Bedside Monitoring Unit (BMU) software to address wireless driver-caused shutdowns, BMU software modifications to address noninvasive blood pressure (NIBP) measurements).
P080020/S008	03/29/2016	Y - 135 Review Tra	GEL-ONE	SEIKAGAKU CORP.	Approval for the use of a newly installed refrigerator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090012/S010	03/02/2016	N - Normal 180 Day	MELAFIND	STRATA SKIN SCIENCES, INC.	Approval for labeling changes.
P090013/S164	03/18/2016	N - Normal 180 Day	CAPSUREFIX MRI SURE AND SCAN LEAD	MEDTRONIC, INC	Approval for a design change to the lead helix electrode and a manufacturing site change and the related update to analytical methods and tightened specifications proposed for drug related elements of the medical devices.
P090013/S215	03/01/2016	R - Real-Time Proc	REVO MRI SURESCAN IPG	MEDTRONIC INC.	Approval for a modified shield fastener bracket.
P090018/S030	03/18/2016	O - Normal 180 Day	ESTEEM	ENVOY MEDICAL CORPORATION	Approval of the following changes to the post-approval study for your device: change in sample size, removal of blinded audiologists, removal of requirement for x-ray of implanted device, change in follow-up point of evaluation and data gathering for safety objective.
P090022/S026	03/28/2016	R - Real-Time Proc	SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Approval to reduce the center thickness of the currently approved Softec Model HD intraocular lens and assign it the new model designation Softec HDM intraocular lens.
P090029/S002	03/11/2016	O - Normal 180 Day	PRESTIGE(R) LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval of the post-approval study protocol.
P100006/S002	03/16/2016	O - Normal 180 Day	AUGMENT BONE GRAFT	BIOMIMETIC THERAPEUTICS, INC.	Approval of the protocol for the ODE Lead PMA Post-Approval Study.
P100009/S017	03/30/2016	S - Special CBE	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval to modify the deployment sequence instructions in the Instructions for Use.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100010/S053	03/11/2016	R - Real-Time Proc	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval of a new part number and component specifications for an internal USB memory drive to address field reports related to inadequate USB drive performance.
P100026/S040	03/15/2016	N - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval of an alternate supplier to manufacture a lead coil assembly, and resultant minor specification tolerance and testing changes.
P100044/S018	03/23/2016	P - Panel Track	PROPEL MINI SINUS IMPLANT	INTERSECT ENT	Approval for the PROPEL Mini Sinus Implant is intended for use in patients >= 18 years of age following ethmoid/ frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening. The PROPEL Mini Sinus Implant separates/dilates surrounding mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces inflammation. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.
P100049/S015	03/02/2016	N - Normal 180 Day	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Approval for updating the labeling with safety and effectiveness data out to five (5) years for the pivotal trial cohort extended follow-up that has been completed and modify the Indications For Use.
P110014/S006	03/14/2016	R - Real-Time Proc	MARGINPROBE SYSTEM	DUNE MEDICAL DEVICES INC	Approval for changes to the console in order to make the console compliant with the European Commission Restriction of the use of certain hazardous substances (RoHS) directive requirements.
P120012/S010	03/07/2016	R - Real-Time Proc	ABBOTT REALTIME HCV GENOTYPE II	ABBOTT MOLECULAR	Approval for revisions to the application specification file for changes to the liquid level sense and pipette aspiration/dispense volumes during the sample preparation extraction process.
P120016/S017	03/24/2016	Y - 135 Review Tra	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Approval for the implementation of additional equipment used to manufacture the key fusing subassembly.
P130011/S003	03/10/2016	Y - 135 Review Tra	THE SOLO SMART STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for extension of the allowable in-process permanence times for two solutions used in the manufacturing process.
P130013/S004	03/18/2016	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE	BOSTON SCIENTIFIC CORP.	Approval of the post-approval study protocol.
P130021/S020	03/25/2016	R - Real-Time Proc	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for reducing the pre-implantation rinsing time for the CoreValve Evolut R Transcatheter Aortic Valve.
P130024/S010	03/10/2016	R - Real-Time Proc	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval to the addition of a new balloon folding process, implementation of a new in-process leak detection test, changes to the sampling plan for an in-process assay test, and labeling changes for sheath compatibility, crossing profile, and recommended balloon inflation time.
P130026/S017	03/24/2016	R - Real-Time Proc	TACTICATH QUARTZ SET	St. Jude Medical	Approval for modifications to the TactiSys Quartz enclosure, guide light, chassis, and packaging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130026/S017	03/24/2016	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for modifications to the TactiSys Quartz enclosure, guide light, chassis, and packaging.
P140008/S001	03/02/2016	Y - 135 Review Tra	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for the change in venders of manufacturing materials used to mold components of the ORBERA Intragastric Balloon System.
P140015/S006	03/24/2016	R - Real-Time Proc	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Approval for a change in packaging for the replacement pump of the t:slim G4 insulin pump system with Dexcom G4 Platinum CGM.
P140019/S001	03/17/2016	O - Normal 180 Day	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Approval of the protocol for the ODE Lead PMA Post-Approval Study.
P140019/S002	03/18/2016	N - Normal 180 Day	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Approval for the inclusion of additional graft sizes, i.e., 1.0 and 2.5cc, to the approved 5.0cc graft.
P140031/S002	03/16/2016	O - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences Pte., in Singapore, Singapore.
P150011/S002	03/10/2016	Y - 135 Review Tra	THE PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for extension of the allowable in-process permanence times for two solutions used in the manufacturing process.

Total: 59

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S080	03/04/2016	X - 30-Day Notice	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Alternate supplier of blister bowl polymer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790002/S035	03/07/2016	X - 30-Day Notice	BIO OSTEOGEN SYSTEM 204	EBI, LLC	Qualify and approve an alternate supplier to perform the coil covering/sewing manufacturing process and for fabricating an optional accessory extremity band.
P810006/S070	03/17/2016	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Replacement of the current Wet Processing Dispersion Tanks #3 and #4, located in the 105 Morgan Lane Medical Manufacturing Suite Room 407, used to produce collagen dispersions for medical devices. Both of these tanks will be replaced by Wet Processing Dispersion Tanks #6 and #5, respectively. Both tanks are fabricated by the same vendor and according to the same specifications and drawings as the existing tank.
P820033/S010	03/09/2016	X - 30-Day Notice	PLASMAFLO OP-05 W(A) ASAHI PLASMA SEPARATOR	ASAHI KASEI MEDICAL CO., LTD.	Implementation of a new manufacturing site for the vendor [Neat Co., Ltd.] of the GD cap component of the Plasmaflo OP-05W(A) device.
P840001/S322	03/10/2016	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Alternate supplier of capacitors used in the manufacture of hybrid subassemblies for Restore SCS and Activa DBS systems.
P840001/S323	03/08/2016	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Changes to test sample sizes and control limits, changes to the surface treatment and cleaning processes of metal subcomponents, and transfer of receiving and incoming inspection activities for device components to alternate facilities used in the manufacture of SCS lead kits.
P840001/S324	03/30/2016	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Acceptance of a new peel test monitoring process for blister trays and new peel tester equipment for the impacted products, as well as process parameter changes and other minor process updates for the package sealing, tray cleaning, and packaging inspection processes at the Rice Creek Facility.
P840001/S325	03/31/2016	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Assembly of hybrid assemblies manufactured at Medtronic Tempe Campus using the Assembleon Pick and Place machine.
P840062/S055	03/17/2016	X - 30-Day Notice	COLLACOTE(TM)	COLLA-TEC, INC.	Replacement of the current Wet Processing Dispersion Tanks #3 and #4, located in the 105 Morgan Lane Medical Manufacturing Suite Room 407, used to produce collagen dispersions for medical devices. Both of these tanks will be replaced by Wet Processing Dispersion Tanks #6 and #5, respectively. Both tanks are fabricated by the same vendor and according to the same specifications and drawings as the existing tank.
P850010/S069	03/17/2016	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	COLLA-TEC, INC.	Replacement of the current Wet Processing Dispersion Tanks #3 and #4, located in the 105 Morgan Lane Medical Manufacturing Suite Room 407, used to produce collagen dispersions for medical devices. Both of these tanks will be replaced by Wet Processing Dispersion Tanks #6 and #5, respectively. Both tanks are fabricated by the same vendor and according to the same specifications and drawings as the existing tank.
P850079/S070	03/09/2016	X - 30-Day Notice	HYDRASOFT (METHAFILCON B) CONTACT LENS	COOPERVISION, INC.	Transfer of the frequency Xcel toric core cylinder powers -0.75, -1.25, -1.75 and -2.25D dry molding manufacturing process from Dry Line S to Dry Line 1.
P860004/S247	03/31/2016	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Assembly of hybrid assemblies manufactured at Medtronic Tempe Campus using the Assembleon Pick and Place machine.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S143	03/17/2016	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Relocation of the Quality Center labs and associated equipment at the Edwards, Changi, Singapore facility.
P860057/S144	03/18/2016	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Add a vendor for bovine pericardial tissue.
P860057/S145	03/22/2016	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Additional abattoir for bovine pericardium.
P870076/S021	03/02/2016	X - 30-Day Notice	DISPOSABLE FALOPE-RING BAND APPLICATOR KITS	GYRUS ACMI, INC.	Change in supplier from Senior Operations LLC (formerly known as GA MFG Precision) to XL Precision for the manufacture of the Trocar Knife (Part No. 004556-503) and a manufacturing process change to produce a one-piece configuration Trocar Knife.
P900056/S152	03/11/2016	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Change to the catheter component inspection process.
P910018/S018	03/10/2016	X - 30-Day Notice	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Change of vendor (and manufacturing site) of brominated polycarbonate for the housing and header components in the LIPOSORBER LA-15 Systems SULFLUX KP-05.
P920015/S174	03/16/2016	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of the following previously accepted manufacturing change: select final repackaging manufacturing activities at Medtronics Memphis Distribution Center in Memphis, Tennessee.
P920047/S089	03/04/2016	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for components that are utilized in electrophysiology catheters.
P920047/S090	03/04/2016	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Acceptance of alternate vendor for catheter tips.
P950029/S109	03/01/2016	X - 30-Day Notice	Reply SR, Reply DR, Esprit SR, Esprit DR	SORIN GROUP- CRM	Change in the sequence of some manufacturing steps and in the temperature applied during a drying and a curing step.
P960009/S247	03/10/2016	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Alternate supplier of capacitors used in the manufacture of hybrid subassemblies for Restore SCS and Activa DBS systems.
P960009/S248	03/31/2016	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Assembly of hybrid assemblies manufactured at Medtronic Tempe Campus using the Assembleon Pick and Place machine.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960016/S062	03/31/2016	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	St. Jude Medical	Change from a semi-mechanized ring brazing station to a mechanized ring brazing station.
P960040/S364	03/09/2016	X - 30-Day Notice	Dynagen Models D150, D151, D152, D153; Inogen Models D140, D141, D142, D143; Origen Models D050, D051, D052, D053 ICDS	BOSTON SCIENTIFIC	Vertical integration of the high voltage capacitor can.
P960040/S366	03/23/2016	X - 30-Day Notice	ORIGEN EL ICD D050, D051, D052, D053; ORIGEN MINI ICD D000, D001, D002, D003; DYNAGEN EL ICD D150, D151, D152, D153; DYNAGEN MINI ICD D020, D021, D022, D023; INOGEN EL ICD D140, D141, D142, D143; INOGEN MINI ICD D010, D011, D012, D013; INCEPTATM ICD E160, E161, E162, E163;	BOSTON SCIENTIFIC	Alternate supplier for the battery cathode tab insulator top/bottom.
P970003/S191	03/18/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Addition of DuPonts new (Transition) Tyvek for use in sterile packaging of the VNS Therapy® System products.
P970003/S192	03/23/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Removal of a solvent treatment step from the manufacture of Model 302 Leads at the Costa Rica facility.
P970003/S193	03/24/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Support of Model 105 and Model 106 Final Generator production at Cyberonics Costa Rica facility.
P970003/S194	03/24/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Addition of alternate weld parameters for manufacture of the Model 303 implantable lead at the Costa Rica facility.
P970004/S211	03/31/2016	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Assembly of hybrid assemblies manufactured at Medtronic Tempe Campus using the Assembleon Pick and Place machine.
P970051/S145	03/22/2016	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of alternative suppliers of platinum raw materials.
P970054/S011	03/03/2016	X - 30-Day Notice	PARVOVIRUS B19 IgG ENZYME IMMUNOASSAY (V519GUS)	DIASORIN	Modification of the conjugate optimization process.

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P980003/S065	03/04/2016	X - 30-Day Notice	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for components that are utilized in electrophysiology catheters.
P980016/S567	03/01/2016	X - 30-Day Notice	EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MAXIMO 11 ICD, VIVA AF VR ICD, VISIA AF	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of routine bacterial endotoxin testing.
P980016/S571	03/08/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of the following previously accepted manufacturing changes: 1) the removal of various visual inspections and re-ordering of steps in final packaging; 2) a change to the high voltage capacitor weld monitoring frequency; and 3) an update to the manufacturing execution system to FACTORYworks 9.1 and associated changes.
P980016/S573	03/16/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of the following previously accepted manufacturing change: select final repackaging manufacturing activities at Medtronics Memphis Distribution Center in Memphis, Tennessee.
P980016/S574	03/15/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the post sterilization test.
P980016/S575	03/23/2016	X - 30-Day Notice	Evera S DR ICD DDBC3D1, DDBC3D4; Evera S VR ICD DVBC3D1, DVBC3D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Alternate supplier location and manufacturing process for capacitors.

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P980016/S577	03/23/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of an in-house annealing process for titanium shield subassemblies at a second tier supplier.
P980016/S578	03/30/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change in the manufacturing flow by relocating the board bake step to a different time spot in the manufacturing process.
P980035/S454	03/01/2016	X - 30-Day Notice	ADAPTA VERSA SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, RELIA IPG	MEDTRONIC INC.	Implementation of routine bacterial endotoxin testing.
P980035/S456	03/21/2016	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the accelerometer test system.
P980035/S457	03/11/2016	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Replacement of two pick and place machines with one new system used in hybrid manufacturing.
P980035/S458	03/23/2016	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of an in-house annealing process for titanium shield subassemblies at a second tier supplier.
P980044/S031	03/22/2016	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of manufacturing a raw material for other products.
P990012/S026	03/16/2016	X - 30-Day Notice	ELECSYS HBSAG IMMUNOASSAY, ELECSYS HBSAG CONFIRMATORY, AND PRECICONTROL HBSAG	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P990046/S045	03/09/2016	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Relocate your graft vendor's manufacturing operations to La Ciotat, France.

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P990046/S046	03/10/2016	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Change to an alternate test facility and alternate test method for bacterial endotoxin testing.
P990056/S023	03/16/2016	X - 30-Day Notice	ELECSYS TOTAL PSA IMMUNOASSAY AND TOTAL PSA CALSET	ROCHE DIAGNOSTICS CORP.	Transfer the following manufacturing steps to a new building: Purification of antibodies and proteins and manufacturing of antibodies and proteins labelled with biotin or ruthenium complex. In addition, lyophilization of bulk raw materials necessary for production of Elecsys assays will be moved to another new building.
P000013/S013	03/04/2016	X - 30-Day Notice	TRIDENT CERAMIC INSERT	HOWMEDICA OSTEONICS CORP.	Upgrades to the systems at a vendor.
P000027/S022	03/16/2016	X - 30-Day Notice	ELECSYS FREE PSA IMMUNOASSAY/CALSET/ CALCHECK	ROCHE DIAGNOSTICS CORP.	Transfer the following manufacturing steps to a new building: Purification of antibodies and proteins and manufacturing of antibodies and proteins labelled with biotin or ruthenium complex. In addition, lyophilization of bulk raw materials necessary for production of Elecsys assays will be moved to another new building.
P000030/S001	03/14/2016	X - 30-Day Notice	FOCUS NIGHT & DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Revision of internal procedures to harmonize the nomenclature for identifying the tooling used to manufacture approved contact lenses at the Johor and Atlanta manufacturing facilities; and development and implementation of a plan to validate and verify the fabrication of Lotrafilcon B Toric optical tools at the Johor manufacturing facility.
P000030/S002	03/23/2016	X - 30-Day Notice	FOCUS NIGHT & DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Manufacturing changes to include the installation and qualification of new (i.e., replacement) systems for the production of phosphate buffered saline and for the production of phosphate buffered saline with hydrogen peroxide at the Batam, Indonesia production facility.
P000044/S034	03/30/2016	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS/HBSAG REAGENT PACK,VITROS IMMUNODIAGNOSTIC PRODUCTS CONFIRMATORY KIT, AND VITROS IMMUNR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Addition of an alternate supplier for a raw material.
P010012/S410	03/09/2016	X - 30-Day Notice	Dynagen Models G150, G151, G154, G156, G158; Inogen Models G140, G141, G146, G148; Origen Models G050, G051, G056, G058 CRT-Ds	BOSTON SCIENTIFIC CORP.	Vertical integration of the high voltage capacitor can.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S412	03/23/2016	X - 30-Day Notice	DYNAGEN CRT-D G150, G151, G154; DYNAGEN X4 CRT-D G156, G158; INOGEN CRT-D G140, G141; INOGEN X4 CRT-D G146, G148; ORIGEN CRT-D G050, G051; ORIGEN X4 CRT-D G056, G058; INCEPTA TM ICD N160, N161, N164; ENERGEN TM ICD N140, N141; PUNCTUA TM ICD N050, N051	BOSTON SCIENTIFIC CORP.	Alternate supplier for the battery cathode tab insulator top/bottom.
P010015/S291	03/01/2016	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Implementation of routine bacterial endotoxin testing.
P010015/S293	03/21/2016	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the accelerometer test system.
P010015/S294	03/11/2016	X - 30-Day Notice	Consulta, Syncra, Viva CRT-P	MEDTRONIC INC.	Replacement of two pick and place machines with one new system used in hybrid manufacturing.
P010015/S295	03/23/2016	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of an in-house annealing process for titanium shield subassemblies at a second tier supplier.
P010019/S045	03/09/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Implementation of a Carton Laser Mark Inspection System.
P010019/S046	03/14/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Revision of internal procedures to harmonize the nomenclature for identifying the tooling used to manufacture approved contact lenses at the Johor and Atlanta manufacturing facilities; and development and implementation of a plan to validate and verify the fabrication of Lotrafilcon B Toric optical tools at the Johor manufacturing facility.
P010019/S047	03/23/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Manufacturing changes to include the installation and qualification of new (i.e., replacement) systems for the production of phosphate buffered saline and for the production of phosphate buffered saline with hydrogen peroxide at the Batam, Indonesia production facility.
P010019/S048	03/23/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Installation and qualification of a new water pre-treatment and a new USP purified water system used in the production of USP purified water at the Batam, Indonesia manufacturing site.
P010019/S049	03/30/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A) SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Moving the 'lens rinsing' step from after the 100% wet lens QA inspection to before the inspection.

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P010031/S528	03/01/2016	X - 30-Day Notice	BRAVA CRT-D, BRAVA QUAD CRT-D, MAXIMO II CRT-D, PROTECTA CRT-D, PROCETA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUARD XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of routine bacterial endotoxin testing.
P010031/S532	03/08/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of the following previously accepted manufacturing changes: 1) the removal of various visual inspections and re-ordering of steps in final packaging; 2) a change to the high voltage capacitor weld monitoring frequency; and 3) an update to the manufacturing execution system to FACTORYworks 9.1 and associated changes.
P010031/S534	03/16/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of the following previously accepted manufacturing change: select final repackaging manufacturing activities at Medtronics Memphis Distribution Center in Memphis, Tennessee.
P010031/S535	03/15/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the post sterilization test.

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P010031/S536	03/23/2016	X - 30-Day Notice	Brava CRT-D DTBC1D4, DTBC1D1; Brava Quad CRT-D DTBC1Q1, DTBC1QQ; Protecta CRT-D D334 TRM, Protecta CRT-D D334TRG; Protecta XT CRT-D D314TRM, D314TRG; Viva Quad CRT-D DTBB1QQ; Viva Quad S CRT-D DTBB1Q1; Viva Quad XT CRT-D DTBA1Q1; Viva S CRT-D DTBB1D1, DTBB1D4; Viva XT CRT-D DTBA1D1, DTBA1D4, DTBA1QQ	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Alternate supplier location and manufacturing process for capacitors.
P010031/S537	03/23/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an in-house annealing process for titanium shield subassemblies at a second tier supplier.
P010031/S539	03/30/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change in the manufacturing flow by relocating the board bake step to a different time spot in the manufacturing process.
P010032/S113	03/03/2016	X - 30-Day Notice	EON, EONC, EON MINI, PROTEGE, PROTEGE MRI IMPLANTABLE PULSE GENERATORS (IPGS)	St. Jude Medical	Alternate manufacturing location for the SMT Level assemblies used in the manufacturing of the Implantable Pulse Generators (IPGs) and the external accessories for the Spinal Cord Stimulation and Deep Brain Stimulation systems.

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P010054/S028	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P020025/S083	03/04/2016	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Addition of an alternate vendor for components that are utilized in electrophysiology catheters.
P020025/S084	03/04/2016	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Acceptance of alternate vendor for catheter tips.
P030004/S010	03/31/2016	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Additional sterilization chambers for the Apollo Onyx Delivery Microcatheter.
P030009/S083	03/04/2016	X - 30-Day Notice	INTEGRITY RAPID EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC, INC.	Change to the device history recording process.
P030011/S040	03/22/2016	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, INC.	Change in the heat spreader used in the Companion 2 Driver Single Board Computer (SBC).
P030011/S041	03/22/2016	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, INC.	Change to replace an obsolete subcomponent, a common mode filter, on the Companion 2 Driver Main Printed Circuit Board Assembly (PCBA).
P030011/S042	03/17/2016	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, INC.	Change to add three alternate, equivalent subcomponents (one capacitor, two resistors) on the Companion 2 Driver Main Printed Circuit Board Assembly (PCBA).
P030017/S246	03/04/2016	X - 30-Day Notice	PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of a rework process for the carrier subassembly of the 32 Contact Paddle Leads.
P030017/S247	03/18/2016	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Acceptance of an alternate qualified manufacturing site at the BSN Valencia facility for the laser ablation of the multi-lumen tubes, which are used in the assembly of the Infinion and Infinion CX 16 Contact Leads of the Precision, Precision Spectra, and Precision Novi Spinal Cord Stimulation (SCS) Systems

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S248	03/24/2016	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate supplier of the cables used in the Infinion 16 and Infinion CX Leads for the Precision SCS systems.
P040043/S082	03/02/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement a new sewing machine to process the sleeve component of the GORE TAG Thoracic Endoprosthesis.
P040045/S055	03/04/2016	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier of blister bowl polymer.
P050006/S050	03/24/2016	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Add equipment for the HLC dipper process.
P050019/S024	03/17/2016	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Added in-process control for the pouch manufacturing process.
P050023/S096	03/29/2016	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Changes to visual inspection criteria and incoming inspection sample size for polyurethane tubing.
P050038/S029	03/23/2016	X - 30-Day Notice	ARISTA AH ABSORBABLE HEMOSTAT	C.R. BARD, INC.	Including an additional component supplier.
P050042/S033	03/24/2016	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Add an additional supplier purity specification for an incoming raw material used in the manufacture of the ARCHITECT Anti-HCV Assay.
P060006/S072	03/18/2016	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the stent inspection processes
P060040/S053	03/24/2016	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Qualify a second source supplier for molded parts used in the HeartMate II System.

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P070008/S071	03/29/2016	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Changes to visual inspection criteria and incoming inspection sample size for polyurethane tubing.
P070026/S034	03/23/2016	X - 30-Day Notice	CERAMAX Ceramic Total Hip System	DEPUY ORTHOPAEDICS, INC.	Addition of a 2D barcode manufacturing process and equipment and addition of part identification verification steps to the manufacturing process.
P080011/S041	03/21/2016	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Expansion of the cylinder powers available for Biofinity XR toric lenses.
P080020/S019	03/22/2016	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture Gel-One for the purpose of manufacturing a raw material for other products.
P080025/S106	03/31/2016	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Assembly of hybrid assemblies manufactured at Medtronic Tempe Campus using the Assembleon Pick and Place machine.
P090003/S039	03/18/2016	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	Boston Scientific Corporation	Changes to the stent inspection processes
P090003/S040	03/17/2016	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	Boston Scientific Corporation	Added in-process control for the pouch manufacturing process.
P090007/S015	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HCV IMMUNOASSAY, ELECSYS PRECICONTROL ANTI-HCV FOR USE ON COBAS E411 IMMUNOSSAY ANALYZER	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.

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P090008/S017	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HCV IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HCV FOR USE ON COBAS E601 IMMUNOSSAY ANALYZER	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P090009/S015	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HCV IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HCV FOR USE ON MODULAR ANALYTICS E170 IMMUNOSSAY ANALYZER	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P090013/S216	03/01/2016	X - 30-Day Notice	RENO MRI SURESCAN IPG	MEDTRONIC INC.	Implementation of routine bacterial endotoxin testing.
P090013/S218	03/11/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Replacement of two pick and place machines with one new system used in hybrid manufacturing.
P090013/S219	03/23/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Implementation of an in-house annealing process for titanium shield subassemblies at a second tier supplier.
P100018/S014	03/31/2016	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Additional sterilization chambers for the Pipeline Embolization Device and Pipeline Flex Embolization Device.
P100021/S051	03/03/2016	X - 30-Day Notice	ENDURANT II & ENDURANT IIS STENT GRAFT SYSTEM, ENDURANT II AORTO-UNI-ILIAC STENT GRAFT SYSTEM	MEDTRONIC INC.	Addition of a Delrin fixture for manufacturing of the Tapered Tip Assembly.

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P100021/S051	03/03/2016	X - 30-Day Notice	ENDURANT II & ENDURANT IIS STENT GRAFT SYSTEM, ENDURANT II AORTO-UNI-ILIAC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Addition of a Delrin fixture for manufacturing of the Tapered Tip Assembly.
P100026/S042	03/04/2016	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Change to use a larger chamber for the ethylene oxide (EO) sterilization of RNS® System products at the same approved sterilization facility (Sterigenics, Salt Lake City, Utah).
P100031/S016	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HBC	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P100032/S013	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IMMUNOASSAY, ELECSYS PRECICONTROL ANTI-HBC FOR USE ON THE ELECSYS 2010 IMMUNOASSAY ANALYZER	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P100034/S016	03/18/2016	X - 30-Day Notice	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE, LTD.	Additional servicing and repair location for the Optune System.
P100041/S068	03/18/2016	X - 30-Day Notice	EDWARDS SAPIEN TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add a vendor for bovine pericardial tissue.
P100041/S069	03/22/2016	X - 30-Day Notice	EDWARDS SAPIEN TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional abattoir for bovine pericardium.
P100047/S072	03/17/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Automation of an existing manufacturing process via software revision for the HeartWare Ventricular Assist Device (HVAD).
P100047/S073	03/22/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Modification to the approved internal process challenge device (PCD) utilized for the sterilization process verification of the HeartWare Ventricular Assist System.
P100049/S016	03/02/2016	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Update weld ball formation laser processing parameters at a qualified vendor.

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P110010/S120	03/18/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the stent inspection processes.
P110010/S121	03/23/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the ethylene oxide sterilization product family processing.
P110013/S060	03/04/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC IRELAND	Change to the device history recording process.
P110013/S061	03/09/2016	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Change to the automated device history recording process.
P110013/S062	03/31/2016	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Change to the ethylene oxide sterilization monitoring process.
P110014/S007	03/30/2016	X - 30-Day Notice	DUNE MEDICAL DEVICES MARGINPROBE SYSTEM	DUNE MEDICAL DEVICES INC	Software (Seal Test station production software) used in the production of the Margin Probe component of the system was updated to alter the sequence in which a folder name is assigned to an electronic folder containing data from the Seal Test.
P110019/S081	03/17/2016	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change to the annual stability test plan.

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P110019/S082	03/31/2016	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Changes to the in-process packaging verification sampling plan.
P110021/S055	03/18/2016	X - 30-Day Notice	EDWARDS SAPIEN TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES LLC.	Add a vendor for bovine pericardial tissue.
P110021/S056	03/22/2016	X - 30-Day Notice	EDWARDS SAPIEN TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES LLC.	Additional abattoir for bovine pericardium.
P110022/S017	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P110025/S015	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY & ELECSYS PREICONTROL ANTI-HBC IGM FOR USE ON THE MODULAR ANAYTICS E170 IMMUNOASSAY ANA	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P110031/S014	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY AND ELECSYS PRECICONTROL ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P120007/S008	03/28/2016	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Scale up of the manufacturing process for three solutions used in the Aptima HPV 16 18/45 Genotype assay.
P120010/S083	03/23/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Manufacturing facility move by Medtronics Enlite sensor substrate supplier. The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor. The sensor substrate supplier, Metrigraphics, LLC, currently manufactures the Enlite sensor substrate in Wilmington, Massachusetts and will start manufacturing at the new facility in Lowell, Massachusetts. The firm states that the current sensor substrate manufacturing facility will close at the end of lease.
P130005/S011	03/16/2016	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Use for an additional sterilization chamber for the ViperWire component.

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P130007/S010	03/02/2016	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Change in the current Animas Vibe Insulin Pump final QC/kitting process required to implement process improvements to eliminate an unnecessary parts reconciliation process, eliminate process redundancy, and to improve overall manufacturing process efficiency. The Animas Vibe Insulin Pump is a component of the Animas Vibe System.
P130009/S049	03/17/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Relocation of the Quality Center labs and associated equipment at the Edwards, Changi, Singapore facility.
P130009/S050	03/18/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add a vendor for bovine pericardial tissue.
P130009/S051	03/22/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional abattoir for bovine pericardium.
P130015/S006	03/16/2016	X - 30-Day Notice	ELECSYS® HBEAG IMMUNOASSAY AND ELECSYS® PRECICONTROL HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P130016/S018	03/22/2016	X - 30-Day Notice	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of alternative suppliers of platinum raw materials.
P130021/S019	03/06/2016	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Additional sterilization oven for the CoreValve and Evolut R TAV sterilization process.
P130026/S018	03/31/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Changes to a fixture used in the irrigation tubing and luer lock assembly process.
P130028/S003	03/18/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Introduction of an additional IPG radiofrequency communications tuning step for IPG final assemblies.
P130030/S021	03/18/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Changes to the stent inspection processes.

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P130030/S022	03/23/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Change to the ethylene oxide sterilization product family processing.
P140009/S012	03/03/2016	X - 30-Day Notice	BRIO IMPLANTABLE PULSE GENERATORS (IPGS)	St. Jude Medical	Alternate manufacturing location for the SMT Level assemblies used in the manufacturing of the Implantable Pulse Generators (IPGs) and the external accessories for the Spinal Cord Stimulation and Deep Brain Stimulation systems.
P140010/S014	03/29/2016	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Transfer of the drug elution test method.
P140017/S002	03/25/2016	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Addition of a new laser welder in the manufacturing of the Melody Transcatheter Pulmonary Valve frame.
P140021/S006	03/16/2016	X - 30-Day Notice	ELECSYS ANTI-HCV II IMMUNOASSAY, ELECSYS PRECICONTROL ANTI-HCV	ROCHE DIAGNOSTICS OPERATIONS INC	Relocation of manufacturing activities for the purification and production of antibodies and proteins and for the lyophilization of raw materials and addition of new lyophilization equipment.
P140028/S007	03/07/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Update to an in-process catheter inspection.

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P140028/S008	03/21/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Updates to the manufacturing equipment.
P140028/S011	03/30/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Update the existing catheter coating equipment.
P140030/S001	03/10/2016	X - 30-Day Notice	ASTRON STENT SYSTEM	BIOTRONIK, INC.	Removal of a second aeration phase after ethylene oxide sterilization.
P140031/S009	03/18/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add a vendor for bovine pericardial tissue.
P140031/S011	03/22/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Additional abattoir for bovine pericardium.
P140031/S012	03/25/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Addition of an alternate supplier for the SAPIEN 3 Transcatheter Heart Valve frame component.
P150003/S005	03/04/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Equipment updates to the laser welding process.

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P150003/S007	03/18/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Changes to the stent inspection processes.
P150005/S002	03/30/2016	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Change to add three ethylene oxide sterilization chambers to the BSC Coventry Rhode Island facility.
P150014/S001	03/24/2016	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing relocation and process change for a sourced raw material used in the COBAS® systems.
P150015/S001	03/24/2016	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing relocation and process change for a sourced raw material used in the COBAS® systems.
P150019/S001	03/03/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of a new leak tester to the manufacturing process of the Paradigm® REAL-Time family of insulin pumps at Medtronic Puerto Rico Operations Co. (MPROC). The Paradigm REAL-Time insulin pumps are components of the Paradigm REAL-Time Revel System with Enlite Sensor.
P150019/S002	03/03/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Transfer of two sub-assembly processes for the REAL-Time Revel insulin pumps from Medtronic MiniMed in Northridge, CA to Medtronic Puerto Rico Operations Co. (MPROC), Juncos. The Paradigm REAL-Time Revel insulin pumps are components of the Paradigm REAL-Time Revel System with Enlite Sensor.
P150019/S003	03/16/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of an alternate Enlite sensor automated hybrid manufacturing line (Enlite Automation Hybrid Line). The Enlite sensor is a component of the Paradigm REAL-Time Revel System with Enlite Sensor.
P150019/S004	03/16/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Manufacturing change in the preparation of the Piezo component of the electronic stack assemblies within the Paradigm REAL-Time Revel insulin pumps; a new preparation fixture is being used to assemble the Piezo component. The Paradigm REAL-Time Revel insulin pump is a component of the Paradigm REAL-Time Revel System with Enlite Sensor.
P150019/S005	03/17/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Transition of the manufacturing of the Tyvek Lids used for packaging the Enlite Sensor component from the suppliers facility in Philadelphia to Oshkosh, Wisconsin. Additionally, the facility transition includes new manufacturing assets including a coater and die cut lid press. The Enlite Sensor is a component of the Paradigm REAL-Time Revel System with Enlite Sensor.
P150019/S006	03/17/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Alternate supplier of Glucose Oxidase used in the fabrication of the Enlite Glucose Sensor. Glucose Oxidase is used in the fabrication of the Enlite Glucose Sensor that is a component of the Paradigm REAL-Time Revel System with Enlite Sensor.

P150019/S008	03/23/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Manufacturing facility move by Medtronics Enlite sensor substrate supplier. The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor. The sensor substrate supplier, Metrigraphics, LLC, currently manufactures the Enlite sensor substrate in Wilmington, Massachusetts and will start manufacturing at the new facility in Lowell, Massachusetts. The firm states that the current sensor substrate manufacturing facility will close at the end of lease.

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